

Detection of Holes in Disposable Nitrile Gloves by Electrical Resistance

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Introduction

The current standardized tests of whole-glove integrity for disposable gloves are visual water-leak tests, which are qualitative in nature. In addition, little is known regarding the sensitivity of such methods with newer disposable glove formulations. The original tests were designed for thicker surgical gloves. Both the American Society for Testing and Materials (Method D6151) and the Food and Drug Administration guidelines for medical-grade examination gloves specify use of a 1 liter water leak test for detecting holes in gloves.^{1,2}

The two main questions this research project addresses are:
1. Can the existing water leak tests reliably detect a small hole with different brands and formulations?
2. Can electrical resistance (ER) improve sensitivity and provide quantitative measures of glove integrity?

Glove failure was measured using ER testing for the detection of pinholes. This method is more sensitive than traditional water-leak testing and can provide quantitative data related to the size of the pinholes in the material.^{3,4} These studies were conducted with thicker, natural latex surgical gloves. An optimized method for use with disposable gloves needed to be developed.

Significance

This research supports the directions set forth by the National Institute for Occupational Safety and Health (NIOSH) under NORA for biological and chemical protective clothing. This research will serve to improve laboratory testing methods of whole-glove integrity.⁵

This study was designed to provide an improved whole-glove test method for assessing pinholes in disposable gloves, which will improve efforts to protect workers against chemical, physical and biological hazards. For emergency response and medical professionals, these efforts will also help protect the health of the public they serve.

Methods

The main stages of the study were:

- Select a range of different nitrile glove types and brand
- Introduce small holes into the thicker region of the glove
- Develop an ER method for the detection of holes
- Test the effectiveness of the water leak test and ER method at detecting known holes



Figure 1. Modified Water Leak Test

Water Leak Test

The water leak test was modified (Figure 1) in this study. To increase sensitivity, stretching in the cuff region was restricted using a 3-inch long coupling between the glove and adjoining water column. The gloves were mounted on a suspended water column and 1 liter of equilibrated water was added to the column. Each glove was observed for leaks immediately following the introduction of water and then after two minutes.

Electrical Resistance

Electrical resistance (in ohms) was measured using a benchtop multimeter (Figure 2). The glove was filled with a conducting salt solution and suspended within a larger container with the same conducting solution (Figure 3). Electrodes were placed inside and outside the glove and the ER recorded after an optimized equilibration time of 4 minutes.

In the absence of pinholes, the resistance will be infinite. In the presence of one or more pinholes, electrical current will pass between the conducting solutions resulting in a measurable ER. The detection limit (DL) was determined by subtracting 3 times the standard deviation from the no-hole mean ($n=15$). The DLs for the five glove brands ranged from 73 to 849 kilo-ohms. Electrical resistance values below the DL indicated a hole was present.



Figure 2. Multimeter

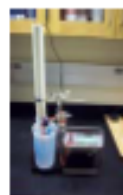


Figure 3. Electrical Resistance Set-up

Results

Part 1.

A 20-gauge needle with 90° point (flat) was used to make round-shaped holes (0.15 ± 0.05 mm) in the glove. Water leak and ER tests were performed on each glove brand ($n=15$).

Both methods successfully detected a hole in all samples.

Part 2.

A 30-gauge lancet with 22° bevel was used to make a crescent-shaped holes. The proportions of false-negatives for the water leak tests (Figure 4) were 6.7, 20, 27, 33, and 47%. The proportions of false-negatives for the ER tests (Figure 5) were 6.7, 0, 53, 100, and 87%, respectively.

Figure 4. Percentage of False-negative Results for the Water Leak Tests

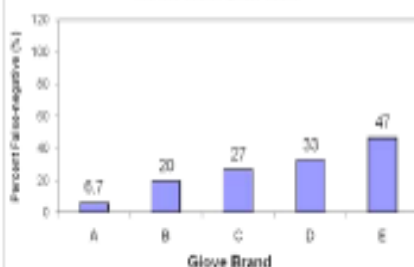
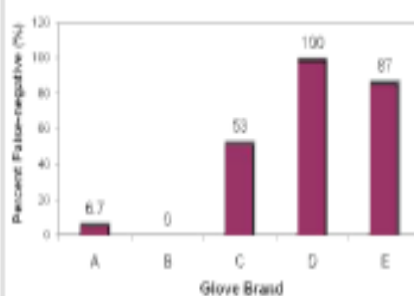


Figure 5. Percentage of False-negative Results for the Electrical Resistance Tests



Conclusions

Neither test was reliable at detecting a small needle hole from a standard beveled tip. Unexpectedly, the existing water leak test did not reliably detect a hole in the finger region.

The problems with the ER method were:

1. There was wide variation in the ER between glove brands
2. There was wide variation in the ER between gloves of the same brand, which impact DLs
3. There was no fast/efficient method for determining the absence of holes < 0.1 mm, to establish reliable DLs

Recommendations

The water leak test was equally problematic, but slight modifications can improve its effectiveness, such as:

- Use a small-bore puncture/needle to standardize the sensitivity
- Use surfactants in the test solution (as with viral penetration and condoms) to decrease water tension and increase sensitivity
- Use mechanical methods (as with condom testing) to manipulate the glove during testing and increase sensitivity

References

1. ASTM Standard Test Method for Rubber Detection of Holes in Medical Gloves, Method D 6151-99, ASTM, Philadelphia, 2002.
2. FDA Medical Glove Guidance Manual, Document shell number 802, FDA, USA.
3. Department of Health and Human Services, Rockville, MD, 1999.
4. Spiller, R.L., et al. Detection of surgical glove integrity. *The American Surgeon* 66 (2000) 802.
5. Jensen, A. and Wilkerson, S. The mechanical and microbiological integrity of surgical gloves. *AVJ* 1, January 79 (2002) 140.
6. Allen, M.R. et al. The anatomy of a defective barrier: Sequential glove leak detection in a surgical and dental environment. *Critical Care Medicine* 30 (1998) 170.
7. NIOSH, "The Green Document: Ten years of leadership advancing the National Occupational Research Agenda", Publication number 2006-121, NIOSH Publications Dissemination, Ohio, 2006.

Acknowledgments

The project was supported by Grant 1R21OH00027-01A2 from CDC-NIOSH. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the National Institute for Occupational Safety and Health.